

REMARKS

Upon entry of the foregoing amendment, claims 1, 3-31, 33-63, and 67-70 are pending for the Examiner's consideration, with claims 1, 31, 63, 68, and 69 being the independent claims. Claims 2, 32, and 64-66 are cancelled herein without prejudice to or disclaimer of the subject matter contained therein, and new claims 67-70 are added. Claims 1, 9, 31, 40, and 63 have been amended herein. Applicants respectfully submit that the foregoing amendments introduce no new matter. In this regard, the Examiner is referred to, for example, paragraphs 00136 and 00143 through 00148, and Figures 16A through 16D and 17A through 17C, of the application as originally filed.

Objections to the Specification

The Examiner has objected to paragraphs 00143, 00144, 00145, and 00149 because of several informalities, which have been amended herein in accordance with the Examiner's suggestion. Paragraph 00151 has been amended herein to make clear that reference number 1800 refers to "means for indicating readiness" as shown, for example, in Figure 18 and described further in paragraphs 00152 through 00158. Applicants respectfully submit that with the amendment to paragraph 00151, no further amendment to paragraphs 00152, 00153, and 00158 is required. Accordingly, Applicants respectfully submit that the amendments made herein overcome the Examiner's objections to the specification.

Rejection Under 35 U.S.C. § 102(e)

The Examiner has rejected claims 1, 2, 3, 8, 9, 14, 16, 18, 25, 27, 28, 29, 31, 32, 33, 37, 40, 46, 48, 50, 57, 59, 60, and 61 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,948,494 to Snow ("the Snow patent"). Independent claims 1 and 31 have been amended herein, thereby rendering this rejection moot.

The Snow patent is directed to a medicament container that has a generally planar upper surface formed from foil, plastic or similar material that may be easily punctured and deformed by a lancing mechanism. The opposing lower surface is formed of a more rigid material that resists punctures, and is concave to form a blister containing medicament. As explained at column 12, lines 26-38 of the Snow patent, Figure 2B shows a lancet 212 that has been moved down so that tapered ends 212a of the lancet have pierced the upper layer 104 of the

medicament container **200**. The tapered ends **212a** force the foil from the upper layer **104** into contact with the upper surface of the wall **164a** defining the receptacle **164**. This pierced material **104a** remains against the wall **164a** (the foil has been sheared and bent past its yield point), so that it provides almost no interference to entrainment or flow of the medicament **216** in the medicament containment area/flow channel **204**.

As is evident from Figures 2B and 3B of the Snow patent, tapered end **212a** is a beveled face that results in a straight cutting or chiseled *edge* that makes first contact with the upper layer **104** of the medicament container. The first cutting edge in the Snow patent is a straight line, like a woodworking chisel. A chiseled edge creates a broad opening at its initiation site (an opening that is square in shape). The broad openings (**254A** and **254B**) created by the lancet can be seen in Figure 4 of the Snow patent, as well as in Figure 2b where **212a** forms pierced material **104a** from upper layer **104**.

Independent claims 1 and 31 are directed to a puncturing device for puncturing a powder capsule (*see*, for example, capsule **219** in Figure 2 and capsule **1700** in Figures 17A-17C). Independent claims 1 and 31 as presented herein recite that a sharp puncturing point, disposed on the distal end of the prong, makes the initial puncture in the powder capsule. As explained in paragraph 00136 and shown in Figure 16C of the application as originally filed, puncturing surface **1630** is a sharp point that makes the initial puncture hole in the receptacle (*e.g.*, capsule **1700**). As recited in independent claims 1 and 31, the sharp puncturing point makes the initial contact with the powder capsule. The first cutting edge is a sharp point, much like a needle. A sharp puncturing point is necessary for successful puncture of a powder capsule due to the limited physical strength of the capsule, and its tendency to buckle rather than pierce. A sharp puncturing point concentrates the cutting forces to initiate puncture with a lower effort. Because a powder capsule has rounded edges, a lancet with a chiseled edge such as that shown in the Snow patent requires a greater force to puncture this rounded surface. The force needed to puncture a powder capsule with a chiseled edge like that shown in the Snow patent would cause the powder capsule to buckle, rather than be punctured. Therefore, the lancet disclosed in the Snow patent, which uses a chiseled or cutting edge as the initial contact, is not suitable for use with a powder capsule because the capsule would buckle, rather than being punctured.

The Snow patent does not disclose or suggest use of a sharp puncturing point to make the initial puncture in a powder capsule as recited in independent claims 1 and 31. Rather, as discussed above, the Snow patent discloses use of a chiseled or cutting edge on surface **212a** to make initial contact with the upper layer **104** of the medicament container. Moreover, because the lancet described in the Snow patent would not be suitable for use with a powder capsule, the Snow patent does not disclose or suggest use of a powder capsule as recited in independent claims 1 and 31. Instead, the Snow patent discloses use of a planar upper surface and a concave lower surface to form a blister medicament container. For at least the foregoing reasons, Applicants respectfully submit that the Snow patent does not anticipate independent claims 1 and 31, or the more narrow claims depending therefrom.

Independent claim 31 further recites a hanging chad that has a free end formed by the sharp puncturing point and the primary cutting edge, and a hinge coupled to the powder capsule formed by the face. Applicants respectfully submit that the Snow patent does not disclose a hanging chad as recited in independent claim 31. As explained at column 12, lines 31-36 of the Snow patent, tapered end **212a** forces the foil from the upper layer **104** into contact with the wall **164a**, and this pierced material **104a** remains against the wall because it has been sheared and bent past its yield point. Pierced material **104a** is not “hanging,” and it does not have a free end because all of the pierced material is against wall **164a**. For this reason as well, Applicants respectfully submit that the Snow patent does not anticipate independent claim 31, or the more narrow claims depending therefrom.

Rejections Under 35 U.S.C. § 103(a)

The Dependent Claims and the Snow Patent

The Examiner has rejected dependent claims 4-7, 10-13, 15, 17, 19, 20-24, 26, 30, 34-38, 41-45, 47, 49, 51-56, 58, and 62 under 35 U.S.C. § 103(a) as being unpatentable over the Snow patent. Each of the foregoing dependent claims depends directly or indirectly from independent claims 1 and 31, which have been amended herein, thereby rendering this rejection moot. As discussed above, the Snow patent does not disclose or suggest the subject matter of independent claims 1 and 31 as presented herein. Accordingly, Applicants respectfully submit that the rejection of the foregoing dependent claims cannot properly be maintained.

Independent Claim 63 and the Snow Patent

The Examiner has rejected independent claim 63 under 35 U.S.C. § 103(a) as being unpatentable over the Snow patent. Independent claim 63 has been amended herein, thereby rendering this rejection moot. Independent claim 63 as presented herein recites that a sharp puncturing point, disposed on the distal end of the prong, makes the initial puncture in the powder capsule. As discussed above with respect to independent claims 1 and 31, the Snow patent does not disclose or suggest use of a sharp puncturing point to make the initial puncture in a powder capsule as recited in independent claim 63. Rather, as discussed above, the Snow patent discloses use of a chiseled or cutting edge on surface **212a** to make initial contact with the upper layer **104** of the medicament container. Moreover, because the lancet described in the Snow patent would not be suitable for use with a powder capsule, the Snow patent does not disclose or suggest use of a powder capsule as recited in independent claim 63. Instead, the Snow patent discloses use of a planar upper surface and a concave lower surface to form a blister medicament container. For at least the foregoing reasons, Applicants respectfully submit that the rejection of claim 63 as being unpatentable over the Snow patent cannot properly be maintained.

Independent claim 63 further requires that the prong is configured to form a hanging chad in a wall of the powder capsule, the powder capsule having a longitudinal axis substantially parallel to the prong and a minor axis substantially perpendicular to the longitudinal axis, the hanging chad being opened to an angle of at least 30 degrees with respect to the minor axis. Applicants respectfully submit that, in addition to not disclosing a powder capsule, the Snow patent does not disclose a hanging chad that is opened to an angle of at least 30 degrees with respect to the minor axis. As discussed above with respect to independent claim 31, the Snow patent does not disclose a hanging chad. As explained at column 12, lines 31-36 of the Snow patent, tapered end **212a** forces the foil from the upper layer **104** into contact with the wall **164a**, and this pierced material **104a** remains against the wall because it has been sheared and bent past its yield point. Consequently, pierced material **104a** is not “hanging.”

On page 7 of the Office Action, the Examiner asserts with respect to claim 63 that “Applicant has not disclosed that opening the chad at least 30 degrees solves any stated

problem.” Applicants respectfully submit that this statement cannot be supported in light of paragraphs 00145 through 00148 of the application as originally filed. As these paragraphs explain, significant improvement in consistency of the emitted dose was obtained using the puncturing device illustrated in Figures 16A through 16D, and as recited in independent claim 63. As explained in paragraph 00146, the U-shaped staple as shown in Figures 7A through 7D had a mean emitted dose of approximately 81.0%, with a standard deviation of 13.3%, and a mean emitted dose of approximately 51.0%, with a standard deviation of approximately 25.3%. In contrast, as noted in paragraph 00148, the puncturing device of Figures 16A through 16D had a mean emitted dose of approximately 89.5%, with a standard deviation of only 4.9%. The puncturing device of Figures 16A through 16D has a higher emitted dose, and significant improvement in consistency (as shown by the significantly lower standard deviation), over the U-shaped staple of Figures 7A through 7D. The consistently high emitted dose was achieved by opening the chad to an angle of at least 30 to 45 degrees. As such, the specification makes clear that opening the chad to an angle of at least 30 to 45 degrees solve the problem of providing a high, and consistent, emitted dose.

Independent Claims 64-66

The Examiner rejected independent claims 64-66 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,298,846 to Ohki *et al.* (“the Ohki patent”) in view of the Snow patent. Claims 64-66 have been cancelled herein, thereby rendering this rejection moot.

New claims 68-70 are directed to a device for emitting powder. Applicants respectfully submit that a rejection of new claims 68-70 based on a combination of the Ohki patent and the Snow patent cannot properly be made for at least the following reasons. First, the combination does not result in the device as recited in claims 68-70. The Examiner acknowledges on page 7 of the Office Action that the Ohki patent “does not disclose the details of the perforating tool,” and asserts that it “would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined lancet mechanism taught by Snow with the device disclosed by Ohki *et al.* for piercing the capsule.” Applicants respectfully submit that neither patent discloses or suggests the structure for the prong as recited in claims 68-70. Each of independent claims 68 and 69 recites that a sharp puncturing point, disposed on

the distal end of the prong, makes the initial puncture in the powder capsule. As discussed above, the Snow patent does not disclose or suggest use of a sharp puncturing point to make the initial puncture in the powder capsule, as recited in independent claims 68 and 69. Rather, as discussed above, the Snow patent discloses use of a chiseled or cutting edge on surface **212a** to make initial contact with the upper layer **104** of the medicament container. As such, even if the device of the Ohki patent could be combined with the lancet of the Snow patent, the device of independent claims 68 and 69 does not result.

Moreover, Applicants respectfully submit that the teachings of the two patents cannot properly be combined for at least the reason that the lancet of the Snow patent would render the Ohki device inoperable, or, at a minimum, significantly alter its mechanism of operation. *See, e.g.,* M.P.E.P. § 2143.01. In order for the Ohki device to operate, the piercing pins must make four holes in the capsule (*see, for example,* holes H1, H1, H1, and H2 and capsule K shown in Figure 9 of the Ohki patent). The four holes are critical to the air flow path that empties the powder from the capsule, and exits the device. As explained above, the lancet of the Snow patent is not suitable for use to puncture a capsule as shown in the Ohki patent because the capsule would buckle or collapse rather than puncture. The lancet of the Snow patent is designed to fold back a planar foil layer, and to not perforate lower layer **164**. If the lancet of the Snow patent was used with the Ohki device, capsule K would buckle or collapse, rather than result in the 4 holes (two in the top and two in the bottom of the capsule) as shown, for example, in Figure 9 of the Ohki patent. This would render the Ohki device inoperable, or, at a minimum, significantly alter its mechanism of operation. For this reason as well, a rejection of new claims 68-70 based upon a combination of the Ohki and Snow patents cannot properly be made.

Other Matters - Information Disclosure Statement

The Examiner states on page 2 of the Office Action that the “information disclosure statement filed 2/5/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed.” Applicants respectfully submit that the Information Disclosure Statement filed on February 5, 2004 complies fully with 37 C.F.R. § 1.98 through operation of 37 C.F.R. § 1.98(d), which the Examiner fails to cite. In particular, 37 C.F.R. § 1.98(d) states that a copy of documents cited in an earlier application are required to be provided *unless* the

earlier application is properly identified in the Information Disclose Statement, and is relied upon for an earlier effective filing date under 35 U.S.C. § 120, and the statement submitted in the earlier application complies with paragraphs (a) through (c) of § 1.98. Applicants respectfully submit that the requirements of § 1.98(d) have been fully met here, and, as such, a copy of the documents identified by the Examiner was not required.

In particular, page 4, item 8 of the Information Disclosure Statement specifically identifies the two earlier applications relied upon for an earlier filing date under 35 U.S.C. § 120 (Appl. Nos. 10/268,059 and 09/835,302). Paragraph 0001 of the application as originally filed, as well as the Application Data Sheet filed February 5, 2004, make clear that the present application relies upon the foregoing two applications for an earlier effective filing date under 35 U.S.C. § 120. The Information Disclosure Statements filed in the earlier applications fully complied with § 1.98(a) - (c). Therefore, Applicants respectfully submit that a copy of the cited foreign patent documents and non-patent literature documents is not required under § 1.98(d). Accordingly, Applicants have re-submitted a PTO/SB/08 listing such foreign and non-patent literature documents, and the Examiner is requested to initial and return a copy of the enclosed form, and to indicate in the official file wrapper of the present application that these documents have been considered.

CONCLUSION

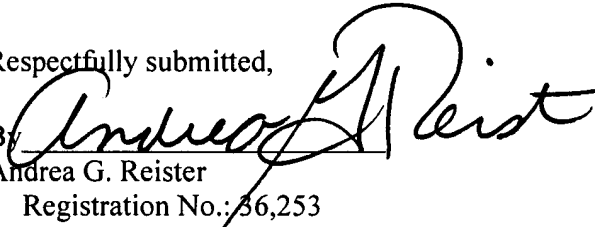
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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